

**Extension to the Memorandum of Understanding for the Health and Safety Executive's delivery of licensing, inspections, investigations and enforcement of the Specified Animal Pathogens Order 2008 -**

**Between the Secretary of State for the Environment, Food and Rural Affairs and the Health and Safety Executive (the Parties)**

**March 2020**

**Extension**

1. In accordance with paragraph 8 of the March 2017 Memorandum of Understanding (MoU) between the Health and Safety Executive and the Secretary of State for the Environment, Food and Rural Affairs, the Parties have mutually agreed to extend this MoU until 31 March 2021.

**Signatories**

2. The duly authorised representative of the Parties affix their signatures below.

We agree to extend the MoU until 31 March 2021 on the same terms of the existing MoU.

**Signed on behalf of the Secretary of State for the Environment, Food and Rural Affairs**

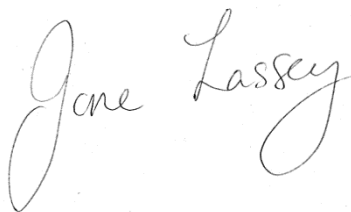


**Print Name: Gordon Hickman**

**Position: Head of Exotic Disease Control**

**Date: 8 April 2020**

**Signed on behalf of the Health and Safety Executive**



**Print Name: Jane Lassey**

**Position: Director, Chemical, Explosives and Microbiological Hazards Division**

**Date .....24/3/20.....**

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**Between the Secretary of State for the Environment, Food and Rural Affairs and the Health and Safety Executive (the Parties)**

**May 2019**

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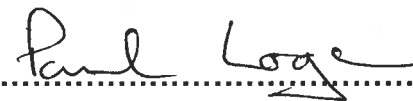
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**Print Name: Peter Jinks**

**Position: Deputy Director, Exotic Disease Policy**

**Date** ..... 3-6-19 .....

**Signed on behalf of the Health and Safety Executive**



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**Print Name: Dr Paul Logan**

**Position: Director, Chemical, Explosives and Microbiological Hazards Division**

**Date** ..... 14-5-19 .....

**Memorandum of Understanding for the Health and Safety Executive's delivery of  
licensing, inspections, investigations and enforcement of the Specified Animal  
Pathogens Order 2008**

**Between the Secretary of State for the Environment, Food and Rural Affairs and  
the Health and Safety Executive (the Parties)**

March 2017

## Background

1. The Specified Animal Pathogens Order 2008 No 944 ('SAPO') prohibits any person from having in their possession any specified animal pathogen listed in Part 1 of Schedule 1 to SAPO or any carrier in which they know such a pathogen is present unless they have a SAPO licence issued by the Secretary of State. It also prohibits the unlicensed introduction into any animal or bird or any pathogen listed in Parts 1 and 2 of Schedule 1 to SAPO.
2. The purpose of SAPO is to prevent the introduction into England and spread of specified animal pathogens, which, if introduced, could cause serious disease and economic loss to the animal and poultry industries. SAPO licences provide a series of goal setting, risk based licence conditions, compliance with which has the cumulative effect of ensuring that specified animal pathogens are adequately contained and managed. Licences are usually valid for 5 years. Inspections of laboratories licensed under SAPO may be carried out at any time to ensure full compliance with licence conditions.
3. The purpose of this Memorandum of Understanding ('MoU') is to set out the framework by which the Health and Safety Executive ('HSE') will provide, deliver and manage the licensing, inspection, investigation and enforcement requirements under SAPO. These are functions exercisable by the Secretary of State either under SAPO or under the Animal Health Act 1981 ('AHA'), which have been transferred to HSE under an Agency Agreement dated 25<sup>th</sup> March 2015 available on [HSE's website](#), being functions which in the opinion of the Secretary of State for Work and Pensions can appropriately be performed by HSE.
4. This MoU will replace the MoU between the Parties signed in June 2015<sup>1</sup>. It is not intended to create a binding legal obligation between the Parties, however the Parties will observe the terms of it.

## Interpretation

5. "Accident" means an unplanned or uncontrolled event involving the escape of a specified animal pathogen from containment.

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<sup>1</sup> Actual date of signing – Defra 16 June 2015, HSE 27 June 2015

6. "Dangerous Occurrence" means an unplanned or uncontrolled event involving a specified animal pathogen that has not resulted in its loss of containment, but which had the potential to do so.

### **Commencement and duration**

7. This MoU shall take effect on the date when it has been signed by all the Parties (the "Commencement Date"). This MoU shall terminate on 31 March 2019, unless terminated early. This MoU will be reviewed by both Parties within 6 months of the termination date, for the purpose of determining if it should be extended, amended or replaced.
8. This MoU may be extended for any further period(s) of 24 months on the same terms and as mutually agreed between the Parties.

### **Statutory obligations**

9. In carrying out the obligations required under this MoU, each Party shall ensure that it complies with all statutory and regulatory requirements in force from time to time, in particular (but not limited to) the following:
  - a. fraud;
  - b. bribery;
  - c. freedom of information;
  - d. confidentiality;
  - e. data protection;
  - f. health and safety.

### **Functions to be performed by HSE**

10. Subject to the limitations set out at paragraph 12, HSE shall perform on behalf of the Secretary of State the following functions:
  - a. issuing licences under Article 4 of SAPO;
  - b. appointment of inspectors under Section 89 of the AHA;
  - c. provide representations, where necessary, to the appointed person under Article 9(2) of SAPO;
  - d. enforcement under Article 11 of SAPO;
  - e. enforcement of Article 65(d) (and annex XII) of Council Directive 2003/85/EC on Community measures for the control of foot-and-mouth disease, as required except where, in the opinion of the HSE, this applies to measures relating to counter-terrorism or general criminal law.

11. In performing the functions set out at paragraph 10, HSE shall:
  - a. comply with the terms of this MoU including the service levels and performance requirements set out at Annex A to this MoU;
  - b. regulate, enforce and investigate licensed facilities in accordance with this MoU, licence conditions, HSE's Enforcement Policy Statement ('EPS'), HSE's Enforcement Management Model ('EMM') and SAPO;
  - c. adopt a regulatory approach that is as far as possible consistent with the existing legislative frameworks for human pathogens and genetically modified organisms. Such an approach shall be coordinated, risk based, goal setting and integrated.

#### **Limitations on functions to be performed by HSE**

12. Nothing in this MoU shall prevent the Secretary of State from exercising any function under SAPO. The Secretary of State shall provide HSE with written notice of their intention to exercise any such function and HSE, having received such notice, will not exercise any such function without the agreement of the Secretary of State.
13. It is established policy that Crown bodies are subject to the same arrangements on specified animal pathogens as all other laboratories. HSE will check their compliance with the SAPO licensing regime in the same manner as for other licence holders. As the licensing, inspection, investigation and enforcement legal powers referred to above are not applicable to Crown bodies, except through established policy and agreement, HSE will utilise an administrative approach to hold Crown bodies accountable. The said administrative approach will be agreed with the Secretary of State.

#### **Undertakings of HSE**

##### **a) Appointment of Inspectors**

14. HSE shall appoint, on behalf of the Secretary of State, members, officers or servants of HSE as Inspectors for the purposes of SAPO and the AHA in so far as it relates to SAPO ('Inspectors').
15. HSE shall ensure that sufficient trained and competent specialist Inspectors are available to undertake and deliver the work agreed for each financial year.
16. HSE Inspectors shall exercise the powers and enforcement functions set out in Articles 6 to 8 and Schedule 2 of SAPO as well as relevant sections of AHA in its application to SAPO.



17. For the avoidance of doubt, the enforcement functions referred to in paragraph 10 include the enforcement of the most current version of the "*Minimum Standards for Laboratories working with Foot and Mouth Disease Virus in vitro/in vivo*", arising from Article 65(d) (and Annex XII) of Council Directive 2003/85/EC on "*community measures for the control of foot-and-mouth disease*" where this is a condition of a SAPO licence. Such enforcement functions do not apply where, in the opinion of HSE, the measures relate to counter-terrorism or general criminal law. "General criminal law" does not extend to conduct which would constitute an offence under SAPO and the AHA.
18. HSE may assign to Inspectors and other members, officers or servants of HSE such duties, and may delegate to any of them such authorities and discretion, as it considers appropriate in order to enforce SAPO.

**b) Content of licences**

19. HSE shall ensure that all SAPO licences include appropriate conditions as reflected in the published guidance "*Guidance for licence holders on the containment and control of specified animal pathogens*" (HSG280) including risk assessment, management arrangements, containment, training and competence, transport, waste management, notification, emergency arrangements, operating procedures, cooperation with Inspectors and (where appropriate) EU requirements.
20. Licences should require licence holders to ensure that their employees, officers or agents at the licensed site cooperate with the Inspector and comply with any requirement imposed by the Inspector with respect to the containment of specified animal pathogens (eg permitting the inspector to enter licensed premises, taking of photographs, making and taking copies of documents and complying with the requirements of enforcement notices).

**c) Accidents and Dangerous Occurrences**

21. HSE shall ensure that the requirements set out in Annex A to this MoU regarding the handling of Accidents and Dangerous Occurrences are complied with.

**Price and payment**

22. The Secretary of State shall pay HSE the costs incurred in performing the functions specified in paragraph 10 in accordance with the following arrangements:
  - a. the Secretary of State shall pay HSE for agreed planned work and for reactive work to support licensing arrangements according to an annual

costed programme of work (the 'Programme of Work'). The Programme of Work will be set out and agreed with the Secretary of State in advance of the financial year. In addition, HSE will provide to the Secretary of State on request, input to inform Spending Reviews;

- b. HSE shall notify the Secretary of State as soon as possible if the agreed sums set out in the Programme of Work are likely to be different;
- c. the Secretary of State shall be responsible for additional costs only where the Secretary of State has consented to that additional expenditure in writing before it has been incurred;
- d. payment for each financial year will be to HSE on a quarterly basis on receipt of a valid invoice. Payment shall be made within 30 days of receipt of an undisputed invoice;
- e. an invoice shall be considered valid where it includes a description of the work and the number of hours spent on planned and reactive work.

### **Reporting**

23. HSE shall submit to the Secretary of State by 30<sup>th</sup> June each year a report on the work carried out in performance of this MoU during the preceding financial year (the 'Annual Report'). The Annual Report must contain:
  - a. an account of the work done under the Programme of Work for the preceding financial year;
  - b. the number of inspection visits undertaken during the preceding financial year;
  - c. the outcome of interventions undertaken during the preceding financial year;
  - d. information on investigation and enforcement action undertaken during the preceding financial year.

### **Record keeping**

24. HSE must maintain an auditable system for receiving, processing and authorising licences. Current and previous licences must be retained in electronic format. All SAPO documents and licences must be kept securely.
25. HSE must ensure that SAPO documents and licences are marked according to the relevant security marking appropriate to each document or licence.

26. HSE shall produce such accounts, documents, records or explanation as the Secretary of State may reasonably request relating to the expenditure, licences issued to interventions undertaken in connection with the MoU. In particular, on a quarterly basis HSE shall provide to the Secretary of State a record of the hours and costs of planned and reactive administration, management and inspections and the budgetary position (the 'Financial Report').
27. HSE shall keep and maintain full and accurate records of the functions exercised under the MoU and all expenditure reimbursed by the Secretary of State for at least six years after the completion of the agreed work. HSE will make such records available for scrutiny free of charge at HSE, by prior arrangement, to auditors acting on behalf of the Secretary of State.
28. The Secretary of State will retain copy files of SAPO documents and licences produced before 1 April 2015 for five years from the last paper on the file.

### **Monitoring of Performance**

29. HSE shall immediately inform the Secretary of State if any of the functions referred to above are not being or are unable to be performed, the reasons for non-performance, any corrective action and the date by which that corrective action will be completed.
30. Performance of the functions referred to above is subject to the provisions set out at Annex A to this MoU. Key performance indicators are also set out at Annex A.
31. Every 6 months, a performance review meeting will be held between the Secretary of State and HSE to review the budget, planned and reactive work, management and delivery of the key performance indicators ('Performance Review Meeting').

### **Variation**

32. Any variation to this MoU, may only be made by mutual consent of the Parties. Either Party may seek to vary the agreed scope of this MoU and work contained in it. Each Party shall give reasonable notice of any major changes it is seeking in order to enable the other Party to respond as quickly as possible.
33. On receipt of a written request from the Secretary of State to vary the agreement, HSE will provide an estimate of the financial, human and other resources necessary to meet the request and shall provide an estimated timetable for effecting the variation requested to the agreed deadline.

34. A variation shall not take effect unless recorded in writing and signed by both Parties.

### **Termination**

35. This MoU or any extension of it may be terminated by either Party.
- a. on the expiry of 6 months' written notice of termination given to the other Party; or
  - b. on the expiry of a shorter period of notice than 6 months as agreed by the Parties.
36. In the event of early termination according to paragraph 35:
- a. HSE will submit for payment by the Secretary of State a certified statement of the costs properly incurred from the date of the last payment, if any, up to the termination date;
  - b. HSE may, in addition to the costs referred to in paragraph 36a, also claim costs that it is legally bound to pay after the termination date as a result of commitments properly incurred before the date of notice of termination, which remain unpaid by the Secretary of State at the date of notice of termination.

### **Disputes**

37. Where there is a difference of opinion between the Secretary of State and HSE on the interpretation of this MoU, or any matter arising from this MoU, the matter will, in the first instance, be referred to the nominated contacts, a list of whom will be agreed, maintained and updated. If they are unable to reach agreement, the matter will be referred to the signatures of this agreement and then to the Secretary of State and the Secretary for Work and Pensions who shall jointly be the final arbiters.

### **Signatories**

38. The duly authorised representative of the Parties affix their signatures below.

We agree to and accept all the terms and conditions of the above MoU.

**Signed on behalf of the Secretary of State for the Environment, Food and Rural Affairs**

  
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**Print Name: Joly Macleod**

**Position: Deputy Director, Exotic Disease Control**

**Date:** ..... 28.02.17 .....

**Signed on behalf of Health and Safety Executive**

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**Print Name: Dr Paul Logan**

**Position: Director, Chemical, Explosives and Microbiological Hazards  
Division**

**Date:** ..... 20-3-17 .....

## Annex A – Service Levels and Performance

### General

1. The Secretary of State will continue to be responsible for specified animals pathogens policy advice and appointing someone to consider and report on any appeal of an enforcement notice as required.
2. HSE will be responsible for the effective administration, licensing, inspection (including targeted interventions), and enforcement of SAPO. In carrying out these responsibilities HSE may seek veterinary advice from Animal and Plant Health Agency (APHA) veterinarians.
3. Where practicable, site visits and inspections under SAPO and the Health and Safety at Work etc Act 1974 by HSE are to be coordinated, to ensure HSE make the most efficient use of travel and subsistence.
4. HSE will undertake other relevant activities (eg reviewing guidance) as agreed with the Secretary of State in the Programme of Work.

### Licensing

5. HSE is to ensure that appropriate procedures are in place for quality assurance of licences before issue.
6. HSE's review of licence applications should consider the information in '*Guidance for licence holders on the containment and control of specified animal pathogens*' (HSG280) which sets out the different containment levels i.e. SAPO 2-4.
7. The Parties intend that licensing of SAPO2 facilities will be mainly dealt with through a desk based assessment, unless there is a risk based rationale for a pre-licensing check.
8. The Parties intend that licensing of SAPO3 and SAPO4 facilities will be dealt with by pre-licensing inspection unless there is a risk based rationale for doing this administratively. Where a laboratory applies to work with foot-and-mouth-disease virus for the first time, HSE will notify the Secretary of State. This will enable the Secretary of State to inform the European Commission and an amendment to Part A of Annex XI to Directive 2003/85/EC can be applied for, where required.
9. Licences shall have goal-setting, risk based conditions, which will place an emphasis on safety management systems and the selection of containment and

control measures based on the outcome of risk assessment(s). Examples of such licence conditions are set out in *'Guidance for licence holders on the containment and control of specified animal pathogens'* (HSG280).

10. Licence conditions are to be as consistent as possible across SAPO2, SAPO3 and SAPO4 facilities to provide a consistent regulatory approach by HSE.

### **Reporting and handling of Accidents and Dangerous Occurrences**

11. Licence holders are required to notify HSE of Accidents immediately and Dangerous Occurrences within 24 hours of an Accident or Dangerous Occurrence occurring.
12. Where an Accident has occurred HSE must inform the APHA Veterinary Exotic Notifiable Diseases Unit as soon as possible after receiving notification from the laboratory at which the Accident has occurred.
13. On receipt of an Accident or Dangerous Occurrences notification, HSE will review and decide within 10 working days whether the Accident or Dangerous Occurrence meets the mandatory investigation selection criteria. HSE shall record the rationale behind decisions to investigate or not investigate. HSE shall conduct investigations in line with HSE procedures and appropriate enforcement action taken in line with the EPS and EMM.
14. Where HSE identifies significant compliance issues arising from an Accident or Dangerous Occurrence that may have policy implications or may generate wider public interest, HSE will provide the Secretary of State with an initial written report within 5 working days of discovering this compliance issue. The Secretary of State is to be kept informed of developments and the outcome of related investigations.
15. Where HSE takes enforcement action in the form of a SAPO prohibition notice it will inform the Secretary of State by the end of the next working day that the notice has been issued and provide information on the proposed action/next steps.
16. Where HSE intends to take enforcement by criminal prosecution or HSE action is subject to judicial review, HSE will inform the Secretary of State by the end of the next working day of that decision. An estimate of the likely timescale and costs of any proceedings will be provided thereafter within five working days.
17. A record of all notified Accidents and Dangerous Occurrences shall be kept by HSE and the significant cases discussed at the 6 monthly Performance Review Meetings.

## **Programme of Work**

18. HSE shall agree the Programme of Work with the Secretary of State before the start of each financial year, which shall include:
  - a. the planned objectives, for example, licence renewal inspections and proactive strategic topic based intervention programme (including intervention plans for SAPO 4) for the forthcoming year;
  - b. HSE resources;
  - c. the cost;
  - d. estimated reactive work and requirement for provision of technical advice, guidance or information relevant to specified animal pathogens (eg technical advice on international standards, attendance at international meetings if necessary).



## Key performance indicators

KPI	Output	Measured
KPI 1 – Responsiveness	<p>HSE issues licences to an appropriate quality within 3 months of receiving a complete application or notification of a significant change, or within 15 working days of all outstanding matters having been resolved</p> <p>Ad hoc enquiries are to be dealt within 30 working days or, if urgent, to the agreed deadline.</p>	<p>HSE will deliver required outputs against agreed timescales – measured at monthly operation performance review meetings and summarised at 6 monthly HSE/Defra meetings</p>
KPI 2 – Assessment of Compliance	<p>HSE carries out regulatory activities, investigations, and where appropriate, enforcement of SAPO licence conditions, with experienced and qualified staff, to meet the requirements of this MoU and HSE's inspection and investigation procedures, and EPS and EMM.</p>	<p>HSE will deliver inspection reports, letters, notices, desk-based reviews and investigation reports to HSE expected quality standards and in line with agreed timescales - measured by data quality checks by Ops Manager (SPC/Admin/74) and summarised at 6 monthly HSE/Defra meetings</p>
KPI 3 – HSE to deliver service improvements to Defra and stakeholders, resource, and costs savings.	<p>HSE through intervention, aims to improve safety performance and raise standards across the biological agents sector and to do so in the most efficient and effective manner. HSE uses intelligence to target inspections to areas of greatest risk</p>	<p>6 monthly HSE/Defra review meetings and Annual Report will include discussion of the following parameters:</p> <p>Targeting of intervention plans</p> <p>Comparison of inspection scores at and between SAPO 4 laboratories</p> <p>Comparison of year on year number of reported accidents and dangerous occurrences for SAPO</p> <p>Review of performance statistics to identify if changes are necessary to improve efficiency &amp; effectiveness</p> <p>Data from periodic feedback</p>

		(eg pulse survey) from stakeholder and licence holders
KPI 4 – Performance against budgeted cost	HSE to deliver the agreed service and Programme of Work on time and within budget	Assessed as part of the Performance Review Meetings